TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
WPT0005	
U.S. APPLICATION NO (IF KNOWN)	
10/009278	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB00/02251	**9 June 2000**	**10 June 1999**

TITLE OF INVENTION
APPARATUS INSTRUMENT AND DEVICE FOR CONDUCTING AN ASSAY

APPLICANT(S) FOR DO/EO/US
David ANDREWES, et al.

Applicant herewith submits to the U.S. Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau)
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)) (unsigned).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 16 below concern document(s) or information included:

11. ☒ PCT Search Report and International Preliminary Examination Report.
12. ☐ An assignment document for recording. A separate cover sheet is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power or attorney and/or address letter.
16. ☒ Other items or information

    Certificate of Mailing by Express Mail and Return Card; IDS, Form 1449 and copies of references; Check for $1,224.00.

JC13 Rec'd PCT/PTO 07 DEC 2001

APPLICATION NO. (If known) 10/009278	APPLICATION NO. (If known)	ATTORNEY'S DOCKET NO. WPT0005

17. ☒ The following fees are submitted (Applicant is small entity)

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5))		CALCULATIONS	
Search Report has been prepared by the EPO or JPO	$		
International preliminary examination fee paid to USPTO (37 CFR 1.482).....	$		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid (37 CFR 1.445(a)(2)) paid to USPTO.....	$		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO...	$1,040.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)...	$		
ENTER APPROPRIATE FEE AMOUNT =	$1040.00	$1,040.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than 20 ☐ 30 ☒ months from the earliest claimed priority date (37 CFR 1.492(e)).		$ 130.00	

CLAIMS	NUMBER FILED		RATE		
Total Claims	23 - 20 =	3	x $ 18.00	$54.00	
Independent Claims	2 - 3 =	0	x $ 84.00	$0	
			+ $280.00	$0	
TOTAL OF ABOVE CALCULATIONS =				$1,224.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28)				$.00	
SUBTOTAL =				$0	
Processing fee of **$130.00** for furnishing the English translation later than 20 ☐ 30 ☐ months from the earliest claimed priority date (37 CFR 1.492(f)).				$0	
TOTAL NATIONAL FEE =				$0	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **$40.00** per property +				+ $0	
TOTAL NATIONAL FEE =				$1,224.00	
				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of $1,224.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1123.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.

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Reg. No. 42,320

Attorney Docket No. WPT0005
Client Matter No. 80469.0005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
UNDER THE PATENT COOPERATION TREATY

In re Application of:	
David ANDREWES, et al.	Examiner: Unassigned
Serial No. Unassigned	Art Unit: Unassigned
Filed: December 7, 2001	
For: MIXING APPARATUS AND METHOD OF MIXING DURING CONDUCTING AN ASSAY	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
2900 Crystal Drive
Arlington, VA 22202-3513

Sir:

Please amend the copy of PCT Patent Publication No. WO 00/76663 A1, filed herewith, as follows:

IN THE CLAIMS

Please amend claims 1–23 according to the attached sheets.

Please cancel claim 24 without prejudice to the subject matter contained therein.

REMARKS

The amendment cancels claim 24, making claims 1–23 pending in the application. The amendment removes the multiple dependent claim format and reference numbers in the claims, and was not made to overcome any prior art references. Support for the amendment can be found in the claims. No new matter has been added by the amendment.

Please consider the pending claims in light of the references cited in the enclosed Information Disclosure Statement. These references were cited in the PCT International Search Report, a copy of which is enclosed for your convenience.

Applicants enclose herewith the fee for filing a continuation application and believe this to be the only fee required for this amendment and response. Should any additional fees be required, please charge Deposit Account 50-1123.

Respectfully submitted,

December 7, 2001

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MARKED-UP VERSION OF THE CLAIMS

1. An apparatus [10,] for use in an assay in which a sample is presented to an instrument, comprising a first inlet [12], a second inlet [14] and an inlet port [16], said inlet port being movable relative to each of said first and second inlets such that the inlet port can be brought into liquid communication with each inlet in turn as required, said inlet port accommodating a filter means or a binder retaining means 18 characterised in that said inlet port is brought into liquid communication with each inlet in turn along a linear path.

2. An apparatus as claimed in claim 1 which is a cartridge.

3. An apparatus as claimed in claim 1 [or 2] comprising a first component [20] including the at least first and second inlets [12, 14], which are or include optical chambers; a second component [30] or components [40, 50] comprising a sample receiving chamber [44] and at least one other chamber [46], said at least one other chamber containing an eluting medium; and a third component [60] comprising said inlet port [16].

4. An apparatus as claimed in claim 3 wherein said third component is slidably disposed below the sample receiving chamber in said second component and above the optical chambers in the first component.

5. An apparatus as claimed in claim 3 [or 4] in which the third component seals the sample receiving chamber of the second component so that liquids stored or pre-loaded into the chamber are only released when the inlet ports formed therein are aligned with the optical chambers in the first component.

6. An apparatus as claimed in claim 5 further comprising additional sealing means.

7. An apparatus as claimed in [any of] claim[s] 3 [to 6] in which the third component is provided with a handle or other means by which it can be moved.

8. An apparatus as claimed in [any of] claim[s] 3 [to 7] in which the second component comprises a resilient component and a cover.

9. An apparatus as claimed in claim 8, in which the resilient component comprises a plug closure.

10. An apparatus as claimed in [any of] claim[s] 3 [to 9] in which the second component comprises a channel within which the third component slides.

11. An apparatus as claimed in [any of the preceding] claim[s] 1 further comprising locator lugs to ensure correct orientation in a measuring instrument.

12. An apparatus as claimed in [any of] claim[s] 3 [to 11] further comprising a plurality of fins projecting from the first component.

13. An apparatus as claimed in [any of the preceding] claim[s] 3 in which the optical chambers are curved.

14. An apparatus as claimed in [any of the preceding] claim[s] 1 comprising air relief tubes.

15. An apparatus as claimed in [any of] claim[s] 3 [to 14] wherein the first component is made of a clear material.

16. An apparatus as claimed in [any of] claim[s] 3 [to 16] in which the second component comprises two parts, a resilient component and a cover.

17. An apparatus as claimed in [any of] claim[s] 3 [to 16] wherein the resilient component comprises an elongate channel into which the third component is slidably mounted.

18. An apparatus as claimed in claim 14 wherein each air relief tube co-operates with an aperture in the slide such that when the inlet port is correctly aligned with each chamber the aperture is aligned with the

associated air relief tube thereby causing an air lock to break thus causing release of the chamber contents through the filter into the inlet there below.

19. An apparatus as claimed in [any of] claim[s] 3 [to 18] wherein the first component comprises windows which are inset from the main apparatus surface.

20. An apparatus as claimed in [any of] claim[s] 3 [to 19] wherein the second component is "I" shaped in cross section.

21. An apparatus as claimed in [any of the preceding] claim[s] 1 wherein the apparatus has a toothed surface which teeth provide a means by which the apparatus can be caused to move along a track of a reading instrument.

22. An instrument for reading a sample presented in an apparatus, comprising a microprocessor operable via a key pad, one or more light emitters and one or more light detectors, a display and driver, an analogue to digital converter, and means for connecting the instrument to a power source, characterised in that the instrument comprises an elongate track adapted. to bring an apparatus into a reading position.

23. An instrument as claimed in claim 22 further comprising a filter for selecting a suitable wavelength.

CLEAN VERSION OF THE CLAIMS

1. An apparatus for use in an assay in which a sample is presented to an instrument, comprising a first inlet, a second inlet and an inlet port, said inlet port being movable relative to each of said first and second inlets such that the inlet port can be brought into liquid communication with each inlet in turn as required, said inlet port accommodating a filter means or a binder retaining means characterized in that said inlet port is brought into liquid communication with each inlet in turn along a linear path.

2. An apparatus as claimed in claim 1 which is a cartridge.

3. An apparatus as claimed in claim 1 comprising a first component including the at least first and second inlets which include optical chambers; a second component or components comprising a sample receiving chamber and at least one other chamber, said at least one other chamber containing an eluting medium; and a third component comprising said inlet port.

4. An apparatus as claimed in claim 3 wherein said third component is slidably disposed below the sample receiving chamber in said second component and above the optical chambers in the first component.

5. An apparatus as claimed in claim 3 in which the third component seals the sample receiving chamber of the second component so that liquids stored or pre-loaded into the chamber are only released when the inlet ports formed therein are aligned with the optical chambers in the first component.

6. An apparatus as claimed in claim 5 further comprising additional sealing means.

7. An apparatus as claimed in claim 3 in which the third component is provided with a handle or other means by which it can be moved.

8. An apparatus as claimed in claim 3 in which the second component comprises a resilient component and a cover.

9. An apparatus as claimed in claim 8, in which the resilient component comprises a plug closure.

10. An apparatus as claimed claim 3 in which the second component comprises a channel within which the third component slides.

11. An apparatus as claimed in claim 1 further comprising locator lugs to ensure correct orientation in a measuring instrument.

12. An apparatus as claimed in claim 3 comprising a plurality of fins projecting from the first component.

13. An apparatus as claimed in claim 3, in which the optical chambers are curved.

14. An apparatus as claimed in claim 3, comprising air relief tubes.

15. An apparatus as claimed claim 3, wherein the first component is made of a clear material.

16. An apparatus as claimed in claim 3 in which the second component comprises two parts, a resilient component and a cover.

17. An apparatus as claimed in claim 3, wherein the resilient component comprises an elongate channel into which the third component is slidably mounted.

18. An apparatus as claimed in claim 14 wherein each air relief tube co-operates with an aperture in the slide such that when the inlet port is correctly aligned with each chamber the aperture is aligned with the associated air relief tube thereby causing an air lock to break thus causing release of the chamber contents through the filter into the inlet there below.

19. An apparatus as claimed in claim 3, wherein the first component comprises windows which are inset from the main apparatus surface.

20. An apparatus as claimed in claim 3, wherein the second component is "I" shaped in cross section.

21. An apparatus as claimed in claim 1 wherein the apparatus has a toothed surface which teeth provide a means by which the apparatus can be caused to move along a track of a reading instrument.

22. An instrument for reading a sample presented in an apparatus, comprising a microprocessor operable via a key pad, a least one light emitter and at lest one light detector, a display and driver, an analogue to digital converter, and a means for connecting the instrument to a power source, characterized in that the instrument comprises an elongate track adapted. to bring an apparatus into a reading position.

23. An instrument as claimed in claim 22 further comprising a filter for selecting a suitable, wavelength.

DESCRIPTION

APPARATUS, INSTRUMENT & DEVICE FOR CONDUCTING AN ASSAY

The present invention relates to an apparatus, instrument and device for conducting an assay. More particularly is relates to a device suitable for use in assaying analyses, for example glycated protein, in a sample, such as for example, blood.

The applicant has devised an apparatus, instrument and device for conducting an assay as disclosed in PCT/GB98/033586. The apparatus comprises a first inlet, a second inlet, and an inlet port, said inlet port being movable relative to each of said first and second inlets such that the inlet port can be brought into liquid communication with each inlet in turn as required, said inlet port accommodating a filter means or a binder retaining means.

In use a sample is separated into a first component fraction and a second component fraction and the component fractions are assayed to determine the presence of one or more analyses in said sample fractions.

The component fractions are read in an instrument comprising a microprocessor operable via a keypad, one or more light emitters and one or more light detectors, a display and driver, an analogue to digital converter and means for connecting the instrument to a power source.

The apparatus takes the form of a carousel. It comprises a base portion having a plurality of chambers including first and second inlets, and a top portion which together with the base portion forms the carousel. A funnel portion comprising an inlet port is in

liquid communication with said inlets.

In use the assay reagents are opened and added sequentially by the user such as a doctor or patient.

It would be desirable to provide an apparatus, instrument and device for conducting an assay which is simpler to use and is less prone to user error. It would also be advantageous if such an apparatus could be produced cheaply.

According to a first aspect of the present invention there is provided an apparatus, for use in an assay in which a sample is presented to an instrument, comprising a first inlet, a second inlet and an inlet port, said inlet port being movable relative to each of said first and second inlets such that the inlet port can be brought into liquid communication with each inlet in turn as required, said inlet port accommodating a filter means or a binder retaining means characterised in that said inlet port is brought into liquid communication with each inlet in turn along a linear path.

Preferably the apparatus takes the from of a cartridge.

Preferably the cartridge comprises a first component including the at least first and second inlets, which are or include optical chambers; a second component or components comprising a sample receiving chamber and at least one other chamber, said at least one other chamber containing an eluting medium; and a third component comprising said inlet port. Said third component is slidably disposed below the receiving chambers in said first component and above the optical chambers in the second component.

Preferably the third component forms a seal between the chamber of the second

component so that liquids stored or pre-loaded into the chambers are only released when the inlet port formed therein is aligned with the chambers. Alignment is achieved by sliding the third component along a linear path. Additional sealing means could, however, be deployed to prevent leakage.

Preferably the third component is provided with a handle or other means by which the component can be moved.

Preferably the apparatus is manufactured in a manner enabling easy filling of the chambers. Thus it is preferred that the second component comprises a resilient component and a cover. Preferably the resilient component comprises a plug closure.

To assemble and fill the apparatus the various components are assembled as follows:

1. The resilient component comprising, for example, three chambers is placed in the cover,

2. The plug closure pivots into place,

3. The assay liquids are poured into the 1st chamber, 2nd chamber and 3rd chamber,

4. The filter and/or binding means is located in the inlet port of the 3rd component and this is slid into the 2nd component,

5. The 1st component, including the 1st and 2nd inlets comprising optical chambers, is clipped into place, thus forming the cartridge.

Preferably the second component comprises a channel within which the 3rd

component slides.

The easier it is to use a product the more acceptable it is. By following a linear path the sequence of operations can be simplified to:

1. Unpack the cartridge;
2. Rest the cartridge on a surface and pull open the closure;
3. Take, for example, a blood sample using a loop;
4. Place the blood sample into the open chamber;
5. Replace the plug closure;
6. Shake the cartridge;
7. Insert the cartridge into an instrument.

The cartridge is designed to be inserted into the instrument in one orientation and is provided with locator lugs to ensure correct orientation.

According to a further aspect of the present invention there is provided an instrument, for reading a sample presented in an apparatus, comprising a microprocessor operable via a key pad, one or more light emitters and one or more light detectors, a display and driver, an analogue to digital converter, and means for connecting the instrument to a power source, characterised in that the instrument comprises an elongate track adapted to bring an apparatus into a reading position.

Preferably the instrument includes a filter for selecting a suitable wavelength.

According to yet a further aspect of the present invention there is provided a device comprising an apparatus and instrument of the invention.

The next series of steps are operated from the instrument. The instrument is designed such that at the completion of the testing the cartridge cannot be removed until returned to the start position. This is to seal the spent cartridge and to have the instrument ready for the next test.

The cartridge provides user simplicity. The cartridge benefits from the following features:

There is only one closure and this cannot be removed.

The first component, which is clear has a plurality of projecting fins on its side which give stability when loading the sample, and unsure correct orientation into the instrument and helps prevent fingerprinting the surface.

The filter is hidden, inaccessible and being totally enclosed is immune to violent shaking.

The liquids, their chambers and the filter slide surfaces are enclosed and are not easily contaminated.

In normal usage the user cannot unintentionally operate the cartridge until installed in the instrument.

In one embodiment the faces of the optical chambers can be curved.

The filter is fully aligned with the chamber apertures before air can enter. This means the product drops by gravity only when the chambers are fully aligned. The aim being fast emptying and agitation. The air tubes are positioned to allow this.

The disposable cartridge has only a few parts.

The cartridge benefits from a non-return snap together assembly.

The cartridge benefits from reduced size compared to a carousel, and can be easily packaged in multiples.

The construction means the cartridge is fully sealed for after-use disposal.

The construction allows for a possible reduction in instrument size.

The invention will be now described, by way of example only, with reference to the following figures in which:

Fig. 1 is a perspective view of a cartridge of the invention.

Fig. 2 is an exploded view showing the component parts of the cartridge of Fig. 1;

Fig. 3 is a cross section through the cartridge of Fig. 1; and

Figs. 4 to 7 show cross-sections of the cartridge in an instrument at various stages during an assay procedure.

Referring to Figs. 1 to 3 the apparatus 10 of the invention takes the form of a cartridge. It comprises a first inlet 12, a second inlet 14 and an inlet port 16. The inlet port 16 comprises a filter 18 capable of retaining a binder retaining means.

The cartridge is constructed from a number of component parts. A first component part 20 is made of a clear material, for example, plastics, most preferably acrylic, and houses optical chambers 12 and 14. An additional chamber 13 is disposed between optical chambers 12 and 14 and functions as a wash chamber.

A second component 30 comprises two parts, a resilient component 40 and a cover 50.

The resilient component 40 comprises an elongate channel 42 (partially obscured) into which a third component 60 is slidably mounted. The third component comprises an inlet port 16 in which is housed a filter and/or binder retaining means 18 and a handle 64.

To construct the cartridge 10 the resilient component 40, which is made of rubber, is placed into cover 50. The rubber component 40 comprises three openings 44, 45, 46, which extend into the elongate channel 42. These openings, which are closed to form sample receiving chambers 24, 25, 26 by slide component 60, house various assay liquids. In the case of an assay for determining glycated and non-glycated proteins in haemoglobin the resulting sample receiving chambers 24, 25, and 26 contain respectively,

1) a buffer and an amino phenylboronate agarose matrix,

2) a wash buffer, and

3) an eluting buffer.

Extending and pivoting from one end of the rubber component 40 is a closure lid 47 which seals an aperture 52 in the cover 50 which leads into the filling chamber 24. At the side of each chamber 24, 25 and 26 is an air relief tube 48 which co-operates with an aperture (not shown) in the slide 60 such that when the inlet port 16 is correctly aligned with each chamber 24, 25 and 26 the aperture is aligned with the associated air relief tube thereby causing an air lock to break thus causing release of the chamber contents through the filter into the inlet there below. The component 40 further comprises a plurality of mating members 49 which allow it to be connected to component parts 20 and 50.

The first component comprises windows 72 and 74 which are inset from the main

cartridge surface 76. By having the article windows inset and having projecting fins 78 on either side of the windows, fingerprints, can be avoided and the component strengthened. The second component 60 is preferably "I" shaped in cross section so that it can run against a number of surfaces ensuring a good sealing and preventing leakage from the respective chambers. It also has a handle 64 which can be held in a reading instrument; preferably on the track on which the cartridge runs.

The cover 50, has a toothed surface 54 which teeth provide a means by which the cartridge can be caused to move along a track 80 of a reading instrument.

To assemble and fill the cartridge the rubber component 40 is placed into the cover 50 and the plug closure 47 pivots to close aperture 52. The test liquids are then poured into the chambers 44, 45 and 46. The 3rd component slide 60, with filter 18 then slid into the channel 42 of the rubber component 40 thereby sealing the chamber 44, 45 and 46. The first component is then clipped into place thereby completing assembly.

The device is used in an assay as follows:

1) The cartridge is unpacked and the closure 47 opened.

2) A finger-prick blood sample is collected into a loop and placed into chamber 44 through aperture 52. The chamber comprises a buffer and an amino phenyl boronate (aPBA) agarose affinity matrix. The chamber is closed and the cartridge inverted several times, causing the red blood cells to be lysed thus liberating the haemoglobin.

3) The tube is left for approximately 60-90 seconds, with occasional inversion, during which the glycated haemoglobin present in the sample binds to the aPBA affinity

matrix.

4) During this time, the apparatus 10, which is designed to be disposable, is placed on the track 80 of an instrument which will read the samples and calculate and display the results (Fig. 4).

5) After about 60-90 seconds incubation, the inlet port 16 of the slide component is caused to move relative to the chambers 44, 45 and 46 and the corresponding chambers 12, 13, and 14. In fact the slide is held in position by locking handle 64 into a stop 82 on the track and the cartridge is caused to move along the track 80 by utilising the teeth 54 on the cover 50 to propel the cartridge.

6) When the inlet port 16 is aligned with the first inlet 12 and the first chamber 44 the first air relief tube 48 is caused to break releasing the contents of the first chamber 44 into contact with the filter 16. (Fig 5) The liquid contents of the chamber drain through the filter and are collected in the optical chamber 12. The aPBA affinity matrix, however, is too large to pass through the filter and therefore collects in the inlet port 16.

7) The liquid contents collect in the first optical chamber which contains the non-glycated haemoglobin present in the original sample, the aPBA affinity matrix collected in the inlet port 16 contains the glycated haemoglobin present in the original sample.

8) On completion of this first step, the instrument progresses to stage 2, which is accomplished by causing the cartridge to move along the track and stop at position 2 (Fig. 6). Again, under direction from the instrument the wash buffer from chamber 45 is released into chamber 13 via inlet port 16 and allowed to drain through. This step is to remove any

non-specifically bound non-glycated haemoglobin from the aPBA affinity matrix that may be present from step 1.

9) The instrument progresses to stage 3 and the contents of the chamber 46 is released into chamber 14 via inlet port 16. The elution buffer removes the glycated haemoglobin from the aPBA affinity matrix. (Fig. 7).

10) During the above the instrument spectrophotometrically measures the absorbance of both the non-glycated and the glycated haemoglobin fractions present in the two optical chambers. Using an algorithm built into the instruments software, the % glycated haemoglobin present in the original whole blood sample is calculated and displayed on the display.

11) The apparatus returns to its starting position, is disconnected from the instrument and is discarded as biohazardous waste. The instrument is then ready to perform the next test.

Whilst the invention has been described with reference to an assay for determining the % levels of glycated haemoglobin, the skilled man will appreciate that the number of inlets and chambers and the assay liquids will vary for other assay systems.

CLAIMS

1. An apparatus 10, for use in an assay in which a sample is presented to an instrument, comprising a first inlet 12, a second inlet 14 and an inlet port 16, said inlet port being movable relative to each of said first and second inlets such that the inlet port can be brought into liquid communication with each inlet in turn as required, said inlet port accommodating a filter means or a binder retaining means 18 characterised in that said inlet port is brought into liquid communication with each inlet in turn along a linear path.

2. An apparatus as claimed in claim 1 which is a cartridge.

3. An apparatus as claimed in claim 1 or 2 comprising a first component 20 including the at least first and second inlets 12,14, which are or include optical chambers; a second component 30 or components 40,50 comprising a sample receiving chamber 44 and at least one other chamber 46, said at least one other chamber containing an eluting medium; and a third component 60 comprising said inlet port 16.

4. An apparatus as claimed in claim 3 wherein said third component is slidably disposed below the sample receiving chamber in said second component and above the optical chambers in the first component.

5. An apparatus as claimed in claim 3 or 4 in which the third component seals the sample receiving chamber of the second component so that liquids stored or pre-loaded into the chamber are only released when the inlet ports formed therein are aligned with the optical chambers in the first component.

6. An apparatus as claimed in claim 5 further comprising additional sealing means.

7. An apparatus as claimed in any of claims 3 to 6 in which the third component is provided with a handle or other means by which it can be moved.

8. An apparatus as claimed in any of claims 3 to 7 in which the second component comprises a resilient component and a cover.

9. An apparatus as claimed in claim 8, in which the resilient component comprises a plug closure.

10. An apparatus as claimed in any of claims 3 to 9 in which the second component comprises a channel within which the third component slides.

11. An apparatus as claimed in any of the preceding claims further comprising locator lugs to ensure correct orientation in a measuring instrument.

12. An apparatus as claimed in any of claims 3 to 11 further comprising a plurality of fins projecting from the first component.

13. An apparatus as claimed in any of the preceding claims in which the optical chambers are curved.

14. An apparatus as claimed in any of the preceding claims comprising air relief tubes.

15. An apparatus as claimed in any of claims 3 to 14 wherein the first component is made of a clear material.

16. An apparatus as claimed in any of claims 3 to 15 in which the second component comprises two parts, a resilient component and a cover.

17. An apparatus as claimed in any of claims 3 to 16 wherein the resilient

component comprises an elongate channel into which the third component is slidably mounted.

18. An apparatus as claimed in claim 14 wherein each air relief tube co-operates with an aperture in the slide such that when the inlet port is correctly aligned with each chamber the aperture is aligned with the associated air relief tube thereby causing an air lock to break thus causing release of the chamber contents through the filter into the inlet there below.

19. An apparatus as claimed in any of claims 3 to 18 wherein the first component comprises windows which are inset from the main apparatus surface.

20. An apparatus as claimed in any of claims 3 to 19 wherein the second component is "I" shaped in cross section.

21. An apparatus as claimed in any of the preceding claims wherein the apparatus has a toothed surface which teeth provide a means by which the apparatus can be caused to move along a track of a reading instrument.

22. An instrument for reading a sample presented in an apparatus, comprising a microprocessor operable via a key pad, one or more light emitters and one or more light detectors, a display and driver, an analogue to digital converter, and means for connecting the instrument to a power source, characterised in that the instrument comprises an elongate track adapted to bring an apparatus into a reading position.

23. An instrument as claimed in claim 22 further comprising a filter for selecting a suitable wavelength.

24. A device comprising an apparatus as claimed in any of claims 1 to 21 and an instrument as claimed in claims 22 and 23.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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PCT

(10) International Publication Number
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(26) Publication Language: English

(30) Priority Data:
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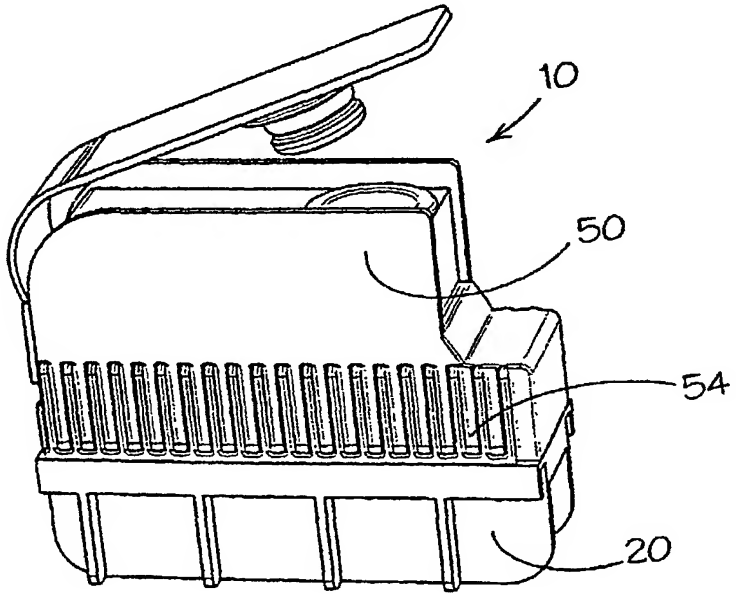
(74) Agent: **W.P. THOMPSON & CO.**; Coopers Building, Church Street, Liverpool L1 3AB (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE,

[Continued on next page]

(54) Title: APPARATUS, INSTRUMENT AND DEVICE FOR CONDUCTING AN ASSAY



(57) Abstract: The present invention relates to an apparatus, instrument and device for conducting an assay. The apparatus comprises a first inlet (12), a second inlet (14) and an inlet port (16) accommodating a filter or binder retaining means, wherein said inlet port is moveable relative to first and second inlets such that the inlet port can be brought into liquid communication with each inlet as required.

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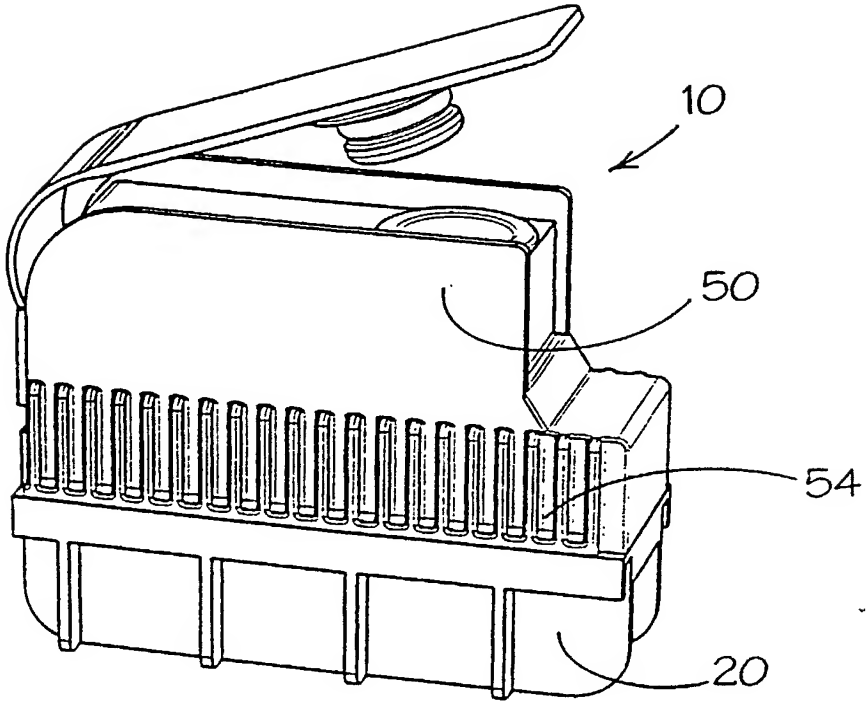

FIG. 1.

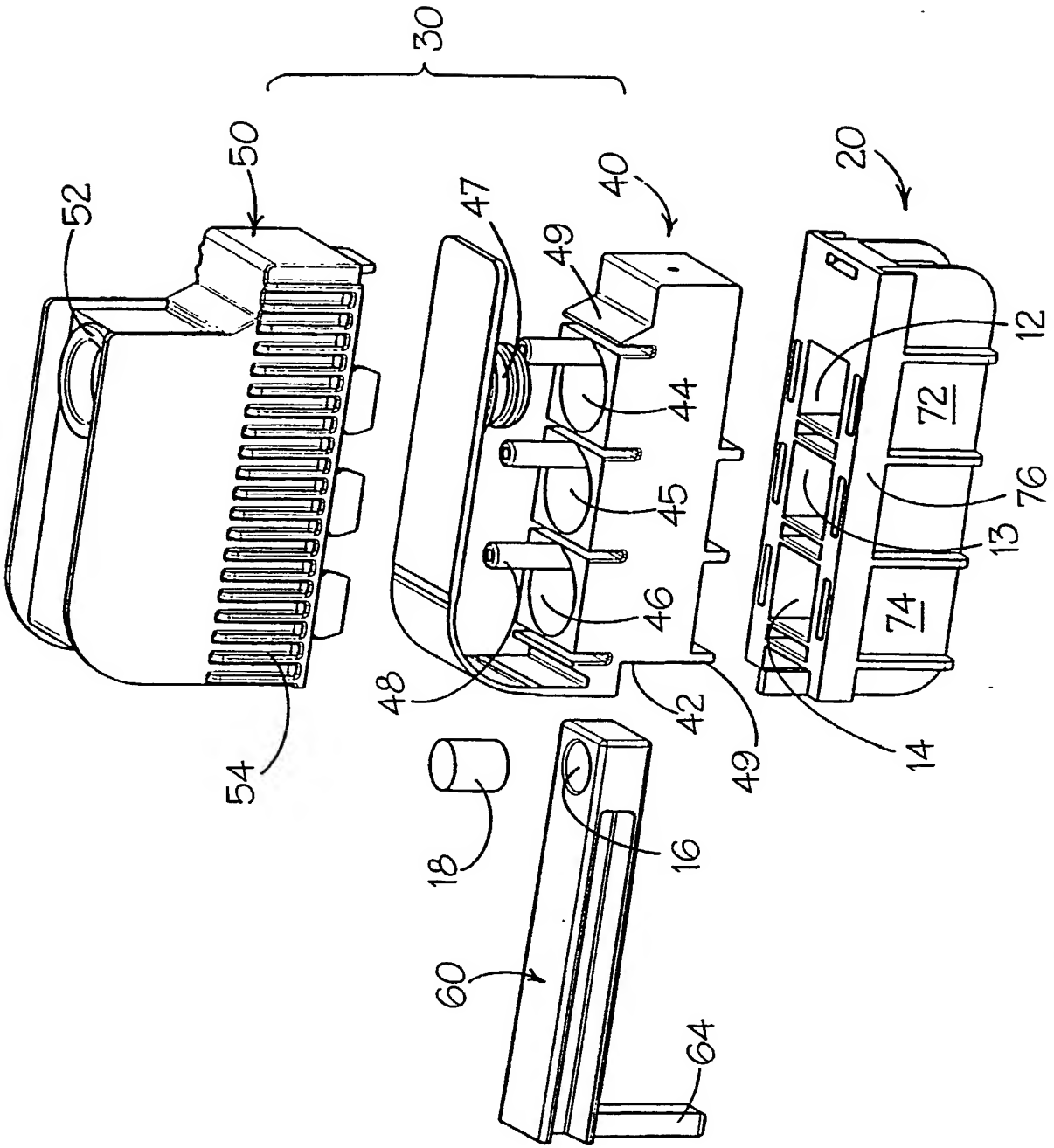

FIG. 2.

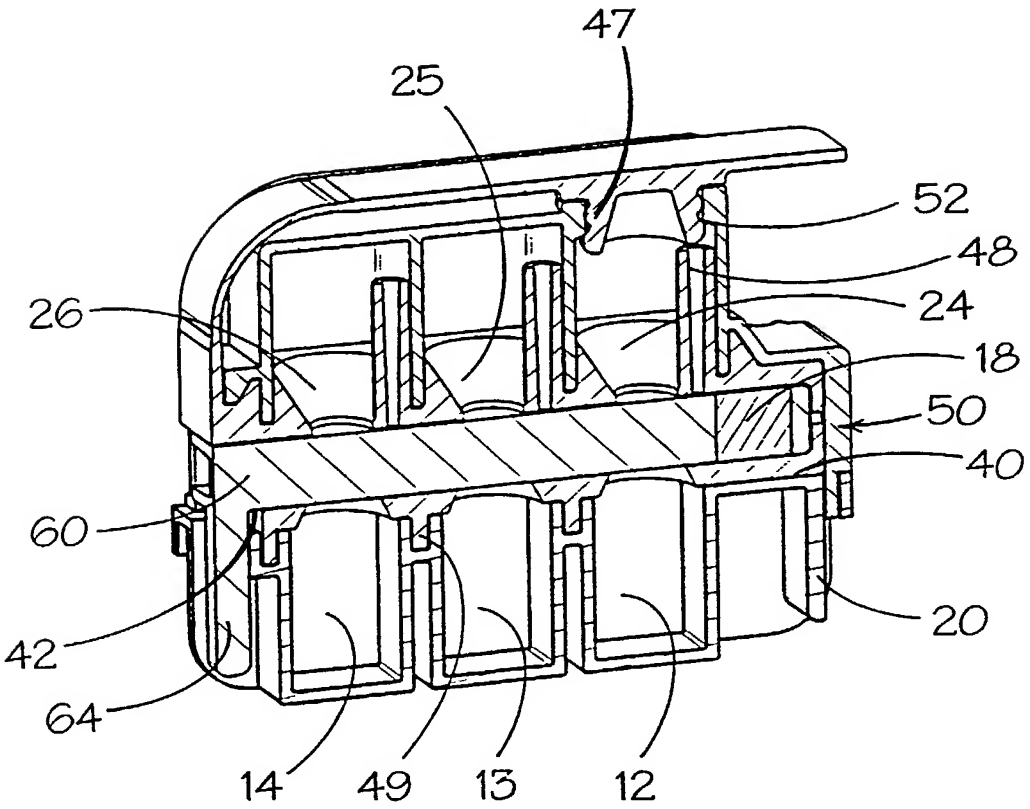

FIG. 3.

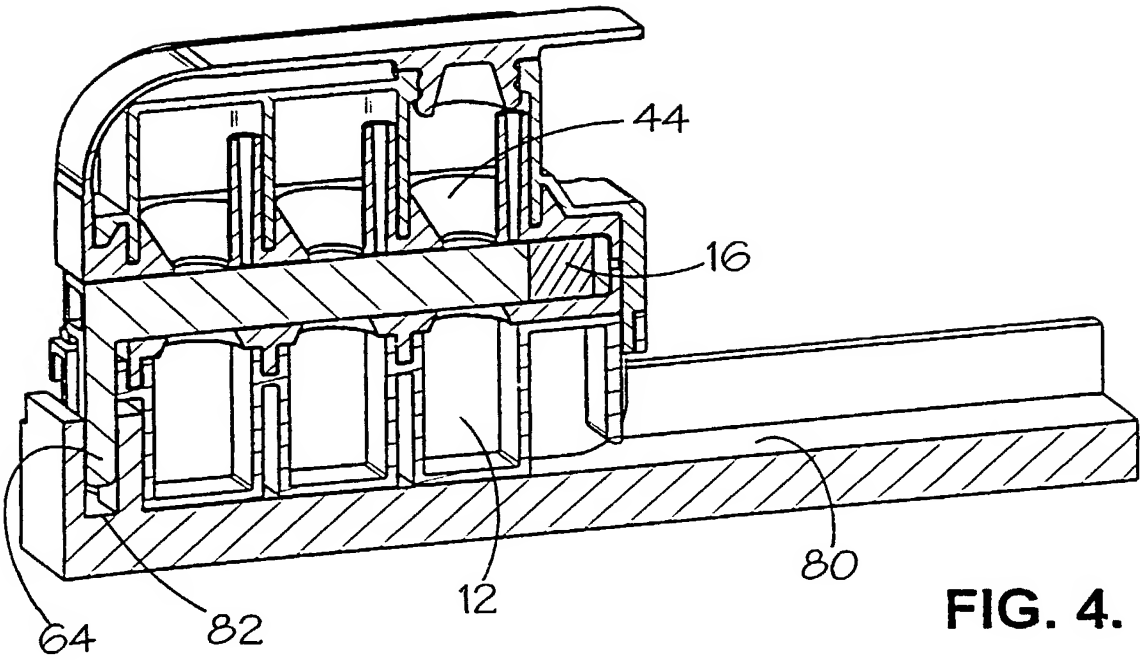

FIG. 4.

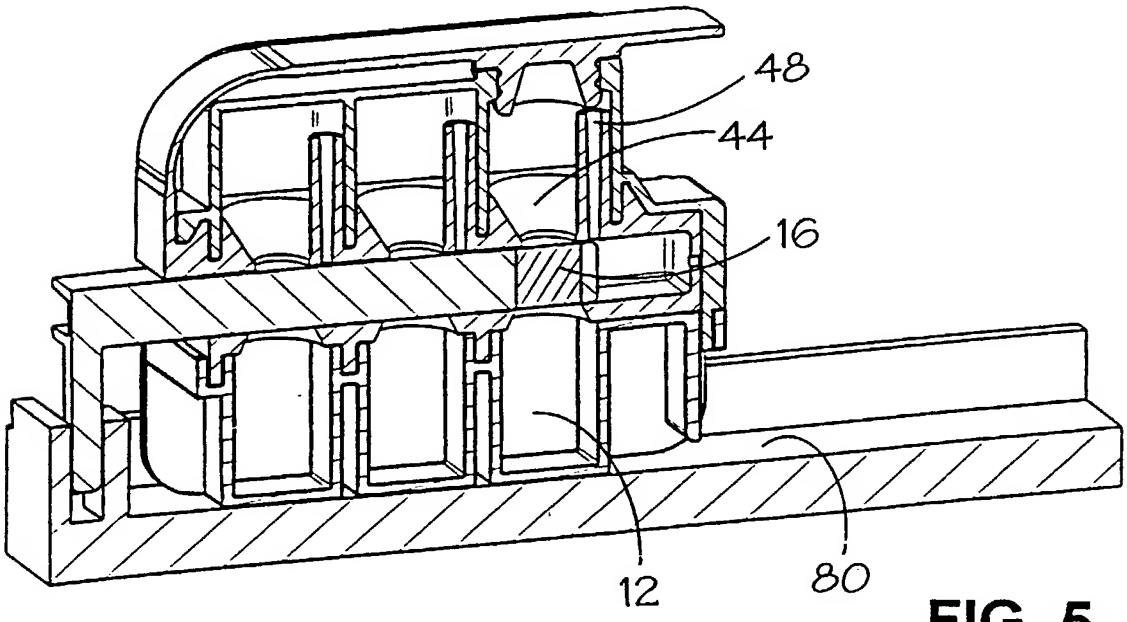

FIG. 5.

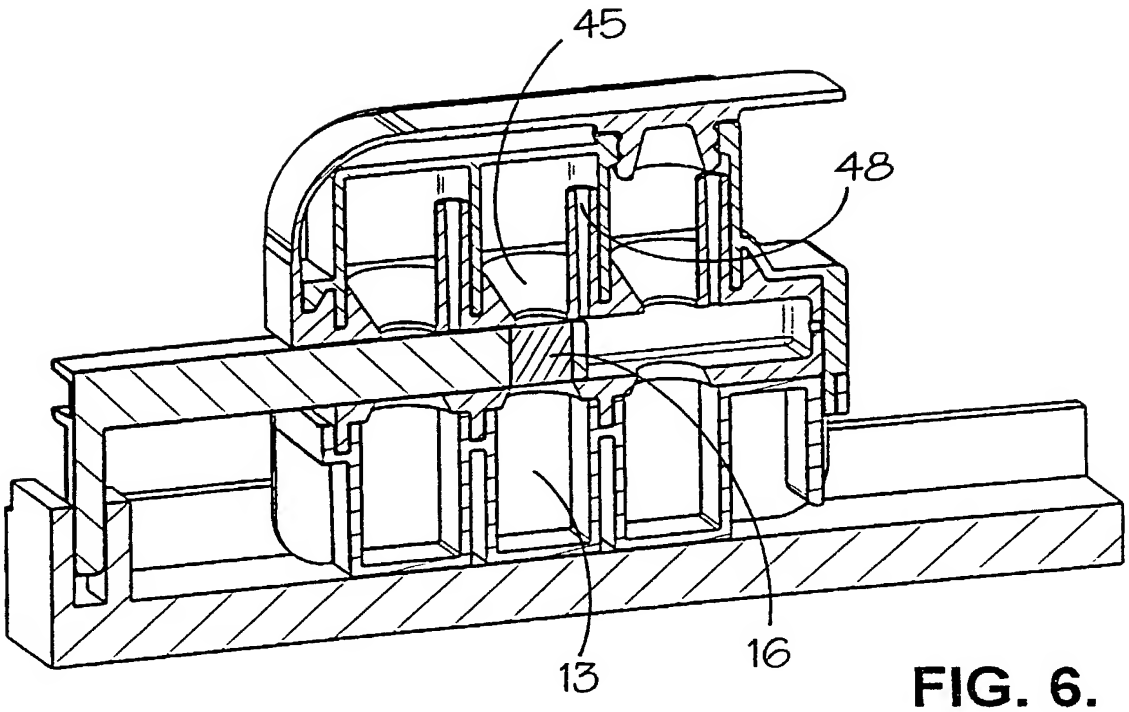

FIG. 6.

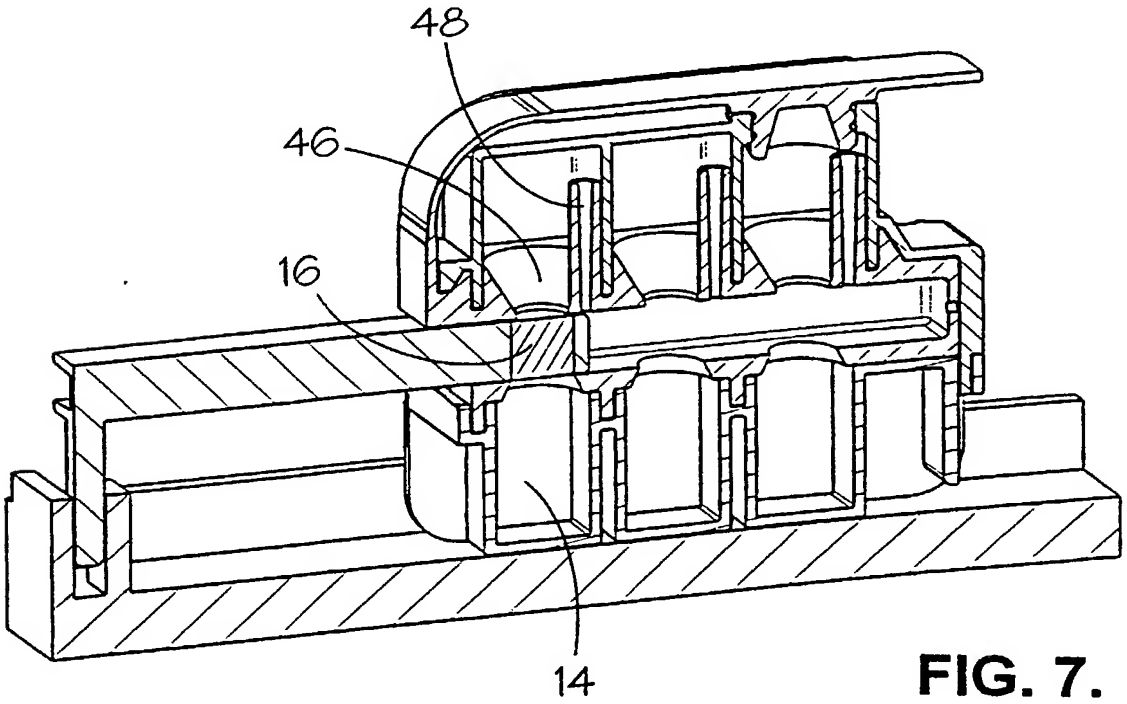

FIG. 7.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☒ Declaration to be Submitted after Initial Filing- surcharge 37 CFR 1.16(e) required

Attorney Docket No.	WPT0005
First Named Inventor	David ANDREWES, et al.
COMPLETE IF KNOWN	
Application Number	10/009,278
Filing Date	December 7, 2001
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that.

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

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the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 12/07/2001

and was amended on (MM/DD/YYYY)

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I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

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9913561.8	GB	06/10/1999	☐	☐	☒
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application nos. are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. § 119(c) of any United States provisional application(s) listed below.

Application Number(s) Filing Date (MM/DD/YYYY)

DECLARATION – Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any U.S. application(s) or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application

U.S. Parent Application or PCT Parent No.	Parent Filing Date (MM/DD/YY)	Parent Patent No. (if applicable)

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As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent Trademark Office connected therewith:

☐ Customer Number
OR
☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number

☐ Additional registered practitioner(s) named on supplemental sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 25235 PATENT TRADEMARK OFFICE OR ☐ Correspondence address below

Name					
Address					
Address					
City			State	ZIP	
Country		Telephone		Fax	

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Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor.

Given Name (first and middle [if any])	Family Name or Surname
David	ANDREWES

Inventor's Signature	D Andrewes							Date	4/6/01
Residence City	Farnham	State	Surrey (GB)	Country	UK	Citizenship	UK		
Post Office Address	5 Ridgeway Road								
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City	Farnham	State	Surrey (GB)	ZIP	GU9 8NN	Country	UK		

☒ Additional inventors are named on 3 supplemental additional inventor(s) sheet(s) PTO/SB/02A attached

DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page 1 of 4

Name of Additional Joint Inventor, if any:			☐ A petition has been filed for this unsigned inventor				
Given Name (first and middle [if any])			Family Name or Surname				
2.00 John Worthington			ATTRIDGE				
Inventor's Signature	John W. Attridge					Date	12/6/02
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Post Office Address	Oakebridge						
Post Office Address	Send Marsh Road						
City	Ripley	State	Surrey (GD)	ZIP	CH23 6JR	Country	UK

Name of Additional Joint Inventor, if any:			☐ A petition has been filed for this unsigned inventor				
Given Name (first and middle [if any])			Family Name or Surname				
2.00 John Philip			VESSEY				
Inventor's Signature	J P Vessey					Date	14.06.02
Residence: City	East Horsley	State	Surrey (GB)	Country	UK	Citizenship	UK
Post Office Address	Canna						
Post Office Address	Forest Road						
City	East Horsley	State	Surrey (GB)	ZIP	KT24 5BT	Country	UK

DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet
Page 2 of 4

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
4-00 Felix	FERNANDO						
Inventor's Signature						Date	11/7/02
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Post Office Address							
City	Wokingham	State	Berks (GB)	ZIP	RG40 2LU	Country	UK

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
5-00 Anthony	STEVENSON						
Inventor's Signature						Date	
Residence: City	Chester	State	Chester (GB)	Country	UK	Citizenship	UK
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Post Office Address							
City	Chester	State	Chester (GB)	ZIP	CH4 8PT	Country	UK

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
6-00 Mark	CRESSWELL						
Inventor's Signature						Date	
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Post Office Address	11 Main Road						
Post Office Address							
City	Broughton	State	Chester (GD)	ZIP	CH4 0NW	Country	UK

DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet
Page 3 of 4

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
7-00 John	CURTIS						
Inventor's Signature						Date	
Residence: City	Balderton	State	Chester (GB)	Country	UK	Citizenship	UK
Post Office Address	Balderton House						
Post Office Address							
City	Balderton	State	Chester (BG)	ZIP	CH4 9FL	Country	UK

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
8-00 David Alan	PERCIVAL						
Inventor's Signature						Date	
Residence: City	Hawarden	State	Flintshire (GB)	Country	UK	Citizenship	UK
Post Office Address	4 Overlea Drive						
Post Office Address							
City	Hawarden	State	Flintshire (GB)	ZIP	CH5 3HS	Country	UK

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Given Name (first and middle [if any])	Family Name or Surname						
9-00 John Anthony	O'DELL						
Inventor's Signature	Anthony Odell					14-6-'02 Date	
Residence: City	Balderton	State	London (GB)	Country	UK	Citizenship	UK
Post Office Address	24 Halford Road						
City	Fulham	State	London (GB)	ZIP	SW6 1JT	Country	UK

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Given Name (first and middle [if any])	Family Name or Surname						
Adrian Richard	GRAY						
Inventor's Signature						Date	
Residence: City	Vaughans Lane	State	Chester (GB)	Country	UK	Citizenship	UK
Post Office Address	West End House						
Post Office Address							
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(if applicable)

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Country		**Telephone**		**Fax**	

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Given Name (first and middle [if any])	Family Name or Surname
David	**ANDREWES**

Inventor's Signature						Date	
Residence City	**Farnham**	State	**Surrey (GB)**	Country	**UK**	Citizenship	**UK**
Post Office Address	**5 Ridgeway Road**						
Post Office Address							
City	**Farnham**	State	**Surrey (GB)**	ZIP	**GU9 8NN**	Country	**UK**

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Page 2 of 4

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Anthony	STEVENSON						
Inventor's Signature	X					Date	03/04/02
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Residence: City		**State**		**Country**		**Citizenship**	
Post Office Address							
Post Office Address							
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Application Number(s) Filing Date (MM/DD/YYYY)

DECLARATION – Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any U.S. application(s) or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application

U.S. Parent Application or PCT Parent No.	Parent Filing Date (MM/DD/YY)	Parent Patent No. (if applicable)

☐ Additional U.S. or PCT international application nos. listed on PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent Trademark Office connected therewith:

☐ Customer Number
OR
☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number

☐ Additional registered practitioner(s) named on supplemental sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 25235 PATENT TRADEMARK OFFICE OR ☐ Correspondence address below

Name					
Address					
Address					
City		**State**		**ZIP**	
Country		**Telephone**		**Fax**	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor.

Given Name (first and middle [if any])	Family Name or Surname
David	**ANDREWES**

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☒Additional inventors are named on 3 supplemental additional inventor(s) sheet(s) PTO/SB/02A attached

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 4

Name of Additional Joint Inventor, if any:			☐ A petition has been filed for this unsigned inventor				
Given Name (first and middle [if any])			Family Name or Surname				
John Worthington			ATTRIDGE				
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Name of Additional Joint Inventor, if any:			☐ A petition has been filed for this unsigned inventor				
Given Name (first and middle [if any])			Family Name or Surname				
John Philip			VESSEY				
Inventor's Signature						Date	
Residence: City	East Horsley	State	Surrey (GB)	Country	UK	Citizenship	UK
Post Office Address	Canna						
Post Office Address	Forest Road						
City	East Horsley	State	Surrey (GB)	ZIP	KT24 5BT	Country	UK

DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page 2 of 4

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
Felix	FERNANDO						
Inventor's Signature					Date		
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Post Office Address	24 Tudor Close						
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City	Wokingham	State	Berks (GB)	ZIP	RG40 2LU	Country	UK

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
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Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
Mark	CRESSWELL						
Inventor's Signature					Date	27/3/02	
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City	Broughton	State	Chester (GB)	ZIP	CH4 0NW	Country	UK

DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page 3 of 4

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
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Inventor's Signature						Date	28.3.02
Residence: City	Balderton	State	Chester (GB)	Country	UK	Citizenship	UK
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Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
David Alan	PERCIVAL						
Inventor's Signature						Date	28/3/02
Residence: City	Hawarden	State	Flintshire (GB)	Country	UK	Citizenship	UK
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Post Office Address							
City	Hawarden	State	Flintshire (GB)	ZIP	CH5 3HS	Country	UK

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
John Anthony	O'DELL						
Inventor's Signature						Date	
Residence: City	Balderton	State	London (GB)	Country	UK	Citizenship	UK
Post Office Address	24 Halford Road						
City	Fulham	State	London (GB)	ZIP	SW6 1JT	Country	UK

DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page 4 of 4

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])	Family Name or Surname						
Adrian Richard	GRAY						
Inventor's Signature					Date		
Residence: City	Vaughans Lane	State	Chester (GB)	Country	UK	Citizenship	UK
Post Office Address	West End House						
Post Office Address							
City	Vaughans Lane	State	Chester (BG)	ZIP	CH3 5XF	Country	UK

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Inventor's Signature					Date		
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☒ Declaration to be Submitted after Initial Filing--surcharge 37 CFR 1.16(e) required

Attorney Docket No.	WPT0005
First Named Inventor	David ANDREWES, et al.
COMPLETE IF KNOWN	
Application Number	10/009,278
Filing Date	December 7, 2001
Group Art Unit	
Examiner Name	

As a below named Inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

APPARATUS INSTRUMENT AND DEVICE FOR CONDUCTING AN ASSAY

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 12/07/2001

and was amended on (MM/DD/YYYY)

as U.S. Application No. or PCT International Application No.

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I hereby claim foreign priority benefits under 35 U.S.C § 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Appl. No.(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? Yes	No
PCT/GB00/02251	WIPO	06/09/2000	☐	☐	☒
9913561.8	GB	06/10/1999	☐	☐	☒
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application nos. are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

Application Number(s) Filing Date (MM/DD/YYYY)

DECLARATION – Utility or Design Patent Application

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Inventor's Signature						Date	
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Post Office Address							
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Post Office Address							
Post Office Address							
City		State		ZIP		Country	